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European patent prosecution & litigation: Supplementary protection certificates

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Speakers, slides & questions

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We welcome any follow up questions by email after the webinar.

SPC case law 2019

- *Teva v Gilead* - C-121/17 and UK courts interpretation
- C-650/17 and C-114/18 – how “specific” must you be?
- C-239/19 – “third party” SPCs
- SPCs and Brexit

SPCs – requirements in EU

Article 3 EU medicines SPC Regulation (469/2009)

(a) Product "protected" by a basic patent in force

(b) Valid marketing authorisation (MA)

(c) Product not already the subject of an SPC

(d) MA is the first MA as a medicinal product

SPCs - *"protected"* by a basic patent

- What is meant by a basic patent *"protects"* a medicinal product for the purposes of Article 3(a) of SPC Regulation?
  - CJEU asked several times before – but no clear answers given
  - Only matter all agree on is that "infringement" test **rejected**
  - Therefore not sufficient for product to simply fall within the claims – *"something more is required"*

Teva v Gilead

- Combination drug - tenofovir disoproxil (“TD”) and emtricitabine – approved for treating HIV

Basic patent:

- Describes and claims TD specifically and combinations generally
  - *“A pharmaceutical composition comprising a compound of claims …and optionally other therapeutic ingredients”*
- No specific example of any combination product
- Does not disclose emtricitabine anywhere

Teva v Gilead – Case history

- SPC granted by UK IPO in 2008
- Several CJEU references on Article 3(a) since then
- Generics sought revocation of SPC before UK Patents Court in 2016
- UK Patents Court unsure on Article 3(a) – what *"more"* is required?
- Referred matter to CJEU (case C-121/17)
- CJEU decision issued summer 2018

CJEU decision C-121/17

- Article 3(a) complied with if, **at basic patent filing date**:

1. the **combination** of active ingredients must necessarily, in the light of the description and drawings of that patent, fall under '*the invention covered by that patent*', and
2. each of those actives must be **specifically identifiable**, in the light of all the information disclosed by that patent

Test 1 – CJEU and UK Patents Ct

- *"Falls under invention"* more specific that just covered by claims
- SPC shouldn't go *"beyond invention patent covers"*
- SPC should *"relate to the results of research claimed under patent"*

UK Patents Court interpreted:

- Product must *"embody technical contribution made by patent"*
- In other words – had patentee actually invented the product?

Test 2 – CJEU and UK Patents Ct

- CJEU less clear on what “specifically identifiable” should mean - but general expression *“other therapeutic ingredients”* not enough
- UK Patents Ct applied this – emtricitabine not mentioned anywhere - therefore SPC invalid
- Gilead appealed to UK Court of Appeal

Questions unanswered

- **Test 1 –** does it apply only to combinations, or also to single actives?
- **Test 2 –** What does *"specifically identifiable"* mean?
  - Must authorized product be specifically disclosed / claimed in patent?
  - Or it is sufficient for patent to describe / claim it more generally?
  - Functional claim?
  - Markush claim?

CJEU referrals C-650/17 & C-114/18

- Both relate to SPCs for single actives
- Both cases: products covered by SPC not specifically disclosed in patent - not developed until after filing date of patent
- Product unarguably falls under general scope of patent claim
  - Functional definition (C-650/17)
  - Markush claim (C-114/18)

CJEU referral C-650/17

Questions referred to CJEU:

1. Is a product protected by a basic patent in force pursuant to Article 3(a) [SPC Reg] only if it forms part of the subject matter of protection defined by the claims and is thus provided to the expert as a specific embodiment?

2. Is it not therefore sufficient for the requirements of Article 3(a) if the product in question satisfies the general functional definition of a class of active ingredients in the claims, but is not otherwise indicated in individualised form as a specific embodiment of the method protected by the basic patent?

3. Is a product not protected by a basic patent in force under Article 3(a) if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?

CJEU referral C-114/18

Question referred to CJEU:

"Where the sole active ingredient is the subject of an SPC … is a member of a class of compounds which fall within a Markush definition in a claim of the patent, all of which class members embody the core inventive technical advance of the patent, is it sufficient for the purposes of Article 3(a) of the SPC Regulation that the compound would, upon examination of its structure, immediately be recognised as one which falls within the class (and therefore would be protected by the patent as a matter of national patent law) or must the specific substituents necessary to form the active ingredient be amongst those which the skilled person could derive, based on their common general knowledge, from a reading of the patent claims?"

C-650/17 & C-114/18 – AG opinion

- Test of C-121/17 should apply both to combination products and single actives
- Provided this test met, Article 3(a) does not, in principle, prevent SPCs from being granted for actives based on basic patents having functional definitions or Markush claims
- However …

C-650/17 & C-114/18 – AG opinion

- **Test 1** not met by product if at basic patent filing date, patent claims in relation to that product are not required for solution of technical problem disclosed by the patent
- **Test 2** not met if, in the light of all the information contained in patent, a product or constituent element of the product remains unknown to skilled person on basis of prior art at patent filing date

C-650/17 & C-114/18

- C-114/18 – request for CJEU reference withdrawn December 2019
- CJEU decision on C-650/17 expected spring 2020

Teva v Gilead - UK Court of Appeal

- Claim must "require" two compounds to "protect" combination
- Each component must be **required** by the claim
- *"… and optionally other therapeutic ingredients"* does not meet this – therefore **Test 1 failed**
- Appeal dismissed
- CA didn't consider whether Test 2 met

Drafting tips for SPCs

- Describe product(s) as specifically as possible
- Include “combinations” section with specific known drugs having same mode of action / same indication
- Where possible, include data for likely combinations of interest
  - Preferably showing improved effect over mono-product(s)

“Third Party” SPCs

- SPC based on another party’s MA **without** the consent of that party
- SPC Reg - SPC granted to holder of basic patent – but silent on whether nexus required between basic patent holder and MA holder
- Not an issue if basic patent holder and MA holder connected, or in licensor-licensee relationship (*Biogen v SKB* C-181/95)
- Uncertain whether SPC Regulation permits “third party” SPCs
- Innovators, generics and NPEs have all tried it!

“Third Party” SPCs - Practice

- Most Patent Offices only check SPC applicant matches patent holder – don’t take identity of MA holder into account
  - At least UK, DE, FR, BE, ES, SE, CH, IT, MT don’t object
  - NL, IS haven’t taken a view on this matter
- UK and DE have granted SPCs to Royalty Pharma Collection Trust for gliptins based on EP1084705 and unconnected third party MAs
  - Same patent as C-650/17 – but “third party” issue not referred

“Third Party” SPCs - C-493/12

- CJEU *obiter* comments on “third party” SPCs:
- *“In such a situation, if an SPC were granted to the patent holder, even though – **since he was not the holder of the MA** granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, **that would undermine the objective** of [the SPC Regulation]”*
- CJEU has not yet decided a case on this issue – but other “third party” SPCs blocked on other grounds (e.g. product not “specified”)

“Third Party” SPCs – C-239/19

- Genentech applied for SPCs for TALTZ (ixekizumab) based on Lilly’s MA – parties unconnected
- Lilly requested declaration that SPC (if granted) would be invalid due to lack of legal relationship between the two
- Lilly indicated they’d seek referral to CJEU to clarify whether or not “third party” SPCs lawful under SPC Regulation
- Patent revoked by UK Patents Court – but “third party” SPC question still referred to CJEU (while UK still can pre-Brexit …)

“Third Party” SPCs – C-239/19

Question referred to CJEU:

- *“Does [SPC Regulation] preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of an MA held by a third party without that party’s consent?*

“Third Party” SPCs – C-239/19

- CJEU order Sep 2019 - referral **inadmissible**
- Question referred “hypothetical” and not necessary to decide upon dispute in referred case
- Brexit irrelevant in deciding admissibility of referral from UK court
- Uncertainty continues (for now) …
- But further referrals likely in future

SPCs and Brexit

- SPCs still available in UK post-Brexit
  - UK national legislation largely replicates SPC Regulations
  - UK national MA required – EU MA not accepted
  - SPC term based on earlier of UK MA and EEA 1st MA
- CJEU case law still applies up to Brexit day
- But UK judges free to diverge after Brexit …

SPCs - Summary

- No clear guidance yet on Article 3(a) – but getting closer?
- “Third party” SPCs still allowable for now – but further reference likely
- UK SPCs allowable post-Brexit – but will case law diverge?

We welcome your questions by email after the webinar.

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